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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,177	03/14/2001	Richard Bruce Roden	031787.0090	2532

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EXAMINER
RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/805,177	Applicant(s) RODEN ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Election facsimile cover sheet* .

DETAILED ACTION

1. Claims 1-45 are pending in the application and are currently subject to a restriction and election requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1, 6-8, 10, 11, and 40, insofar as the claims are drawn to a nucleic acid molecule, a replicon cell comprising at least 18 contiguous residues of said nucleic acid molecule, a recombinant cell containing said replicon, and a kit comprising said nucleic acid molecule or a fragment thereof, classified in class 536, subclass 23.1, class 435, subclass 320.1, class 435, subclass 325, and class 536, subclass 24.3, respectively.

Note: The Office does not have the facilities to determine whether more than one fragment is generated upon the digestion of bacteriophage λ clone 44B.1 with EcoRI and XhoI; however, presumably there is more than one, since the claim reads "a *Exo*RI/*Xho*I fragment" (emphasis added). Accordingly, it cannot be determined whether, for example, claims 1, 2, and 5 encompass the same fragment(s) or different fragments; therefore, claims 1, 2, and 5 have been treated as distinct inventions.

Group 2. Claims 2-4, 6-8, 10, 11, and 40, insofar as the claims are drawn to a nucleic acid molecule, a replicon cell comprising at least 18 contiguous residues of said nucleic acid molecule, a recombinant cell containing said replicon, and a kit comprising said nucleic acid molecule or a fragment thereof, classified in class 536, subclass 23.1, class 435, subclass 320.1, class 435, subclass 325, and class 536, subclass 24.3, respectively.

Groups 3. Claims 5, 10, 11, and 40, insofar as the claims are drawn to a nucleic acid molecule, a replicon cell comprising at least 18 contiguous residues of said nucleic acid molecule, a recombinant cell containing said replicon, and a kit comprising said nucleic acid molecule or a fragment thereof, classified in class 536, subclass 23.1, class 435, subclass 320.1, class 435, subclass 325, and class 536, subclass 24.3, respectively.

Groups 4-6. Claim 9, insofar as the claims are drawn to a pair of nucleic acid molecules, wherein said nucleic acid molecules can be used to amplify a nucleic acid molecule comprising at least 18 contiguous residues of a nucleic acid molecule selected from the group consisting of (a) the nucleic acid molecule of claim 1, (b) the nucleic acid molecule of claim 2, and (c) the nucleic acid molecule of claim 5, classified in class 536, subclass 24.3.

Note: In electing any one of groups 4-6, for example, Applicant is required to specifically identify the nucleic acid molecule to which the claims are to be directed, i.e., (a), (b), or (c).

Groups 7-9. Claims 12-14, insofar as the claims are drawn to a polypeptide, wherein said polypeptide comprises an amino acid sequence encoded by a nucleic acid molecule selected from the group consisting of (a) the nucleic acid molecule of claim 1, (b) the nucleic acid molecule of claim 2, and (c) the nucleic acid molecule of claim 3, classified in class 530, subclass 350.

Groups 10-12. Claims 15, 16, and 39, insofar as the claims are drawn to an antibody, wherein said antibody specifically binds a protein comprising an amino acid sequence encoded by a nucleic acid molecule selected from the group consisting of (a) the nucleic acid molecule of claim 1, (b) the nucleic acid molecule of claim 2, and (c) the nucleic acid molecule of claim 3, and a kit comprising said antibody, classified in class 530, subclass 387.1.

Group 13. Claim 17, insofar as the claim is drawn to a method for selecting a variant nucleic acid molecule, wherein said method comprises screening mammalian DNA with a nucleic acid probe comprising the nucleic acid molecule of claim 1, classified in class 435, subclass 6.

Group 14. Claim 17, insofar as the claim is drawn to a method for selecting a variant nucleic acid molecule, wherein said method comprises screening mammalian DNA with a nucleic acid probe comprising the nucleic acid molecule of claim 2, classified in class 435, subclass 6.

Groups 15-17. Claims 18, 32-38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product encoded by a nucleic acid molecule selected from the group consisting of (a) the nucleic acid molecule of claim 1, (b) the nucleic acid molecule of claim 2, and (c) the nucleic acid molecule of claim 3, wherein said gene product is mRNA, classified in class 435, subclass 4.

Groups 18-20. Claims 18, 31, 32, 37, 38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product encoded by a nucleic acid molecule selected from the group consisting of (a) the nucleic acid molecule of claim 1, (b) the nucleic acid molecule of claim 2, and (c) the nucleic acid molecule of claim 3, wherein said gene product is a protein, classified in class 435, subclass 7.1.

Group 21. Claim 19, drawn to a nucleic acid molecule encoding an amino acid sequence corresponding to the amino acid sequence encoded by the

polynucleotide sequence set forth in SEQ ID NO: 1, classified in class 536, subclass 23.1.

Group 22. Claim 20, drawn to a protein having an amino acid sequence corresponding to the amino acid sequence encoded by the polynucleotide sequence set forth in SEQ ID NO: 1, classified in class 530, subclass 350.

Group 23. Claims 21, 22, 32-38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product encoded by the nucleic acid of claim 19, wherein said gene product is mRNA, classified in class 435, subclass 4.

Group 24. Claims 21, 22, 31, 32, 37, 38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product encoded by the nucleic acid of claim 19, wherein said gene product is a protein, classified in class 435, subclass 7.1.

Group 25. Claims 23-27, 32-38, and 42, insofar as the claims are drawn to a method for screening for cancer or benign tumor in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product of the HOXA7 gene, wherein said gene product is mRNA, classified in class 435, subclass 4.

Group 26. Claims 23-27, 31, 32, 37, 38, and 42, insofar as the claims are drawn to a method for screening for cancer or benign tumor in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product of the HOXA7 gene, wherein said gene product is a protein, classified in class 435, subclass 7.1.

Group 27. Claims 28, 32-38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product of the ATP-dependent iron transporter ABC-7 gene, wherein said gene product is mRNA, classified in class 435, subclass 4.

Group 28. Claims 28, 31, 32, 37, 38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product of the ATP-dependent iron transporter ABC-7 gene, wherein said gene product is a protein, classified in class 435, subclass 7.1.

Group 29. Claims 29, 32-38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product of the ADP-ribosylation factor 1 (Arf-1) gene, wherein said gene product is mRNA, classified in class 435, subclass 4.

Group 30. Claims 29, 31, 32, 37, 38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing a gene product of the ADP-ribosylation factor 1 (Arf-1) gene, wherein said gene product is a protein, classified in class 435, subclass 7.1.

Groups 31-55. Claims 30, 32-38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing two or more gene products selected from the group consisting of (a) the gene product of a ExoRI/XhoI fragment of bacteriophage λ clone 44B.1, wherein said fragment

consists of a nucleic acid molecule selected from the group consisting of (i) the nucleic acid molecule of claim 1, (ii) the nucleic acid molecule of claim 2, and (iii) the nucleic acid molecule of claim 3, (b) the gene product of the HOXA7 gene, (c) the gene product of the HOXB7 gene, (d) the gene product of the ADP-ribosylation factor 1 (Arf-1) gene, and (e) the gene product of the ATP-dependent iron transporter ABC-7 gene, wherein said gene product is mRNA, wherein said classified in class 435, subclass 4.

Note: If electing one of groups 31-55, for example, Applicants are required to specifically identify two or more members of the genus of gene products to which the claims are to be drawn.

Groups 56-80. Claim 30, 31, 32, 37, 38, and 42, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether cells in the individual are expressing two or more gene products selected from the group consisting of (a) the gene product of a ExoRI/XhoI fragment of bacteriophage λ clone 44B.1, wherein said fragment consists of a nucleic acid molecule selected from the group consisting of (i) the nucleic acid molecule of claim 1, (ii) the nucleic acid molecule of claim 2, and (iii) the nucleic acid molecule of claim 3, (b) the gene product of the HOXA7 gene, (c) the gene product of the HOXB7 gene, (d) the gene product of the ADP-ribosylation factor 1 (Arf-1) gene, and (e) the gene product of the ATP-dependent iron transporter ABC-7 gene, wherein said gene product is a protein, classified in class 435, subclass 7.1.

Groups 81-110. Claim 41, insofar as the claims are drawn to a method for screening for cancer in an individual, wherein said method comprises determining whether a sample of said individual's body fluid contains antibodies specific for one or more of the proteins selected from the group consisting of (a)

the gene product of a ExoRI/XhoI fragment of bacteriophage λ clone 44B.1, wherein said fragment consists of a nucleic acid molecule selected from the group consisting of (i) the nucleic acid molecule of claim 1, (ii) the nucleic acid molecule of claim 2, and (iii) the nucleic acid molecule of claim 3, (b) the gene product of the HOXA7 gene, (c) the gene product of the HOXB7 gene, (d) the gene product of the ADP-ribosylation factor 1 (Arf-1) gene, and (e) the gene product of the ATP-dependent iron transporter ABC-7 gene, classified in class 435, subclass 7.1.

Groups 111-140. Claims 43-45, insofar as the claims are drawn to a method for treating an individual, wherein said method comprises administering to said individual one or more of the proteins or at least one or more of the epitopes thereof selected from the group consisting of (a) the gene product of a ExoRI/XhoI fragment of bacteriophage λ clone 44B.1, wherein said fragment consists of a nucleic acid molecule selected from the group consisting of (i) the nucleic acid molecule of claim 1, (ii) the nucleic acid molecule of claim 2, and (iii) the nucleic acid molecule of claim 3, (b) the gene product of the HOXA7 gene, (c) the gene product of the HOXB7 gene, (d) the gene product of the ADP-ribosylation factor 1 (Arf-1) gene, and (e) the gene product of the ATP-dependent iron transporter ABC-7 gene, classified in class 424, subclass 277.1.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions in groups 1-12, 21, and 22 are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods. Therefore, the claimed products in each of groups 1-12, 21, and 22 are distinct from the claimed products of the other groups.

The inventions in groups 13-20 and 23-140 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria

for success. Therefore, the claimed methods in each of groups 13-20 and 23-140 are distinct from the claimed methods of the other groups.

The inventions in groups 1 and 2 and groups 13 and 14, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the nucleic acid molecule can be used in a materially different process of using that product, such as the process of using the nucleic acid molecule to produce the protein encoded by the nucleic acid molecule.

The inventions in groups 1 and 2 and groups 15-20 and 23-140 are not at all related because the products of groups 1 and 2 are not specifically used in any of the steps of the claimed method in groups 15-20 and 23-140.

The inventions in groups 3-12, 21, and 22 and groups 13-20 and 23-140 are not at all related because the products of groups 3-12, 21, and 22 are not specifically used in any of the steps of the claimed method in groups 13-20 and 23-140.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

slr
July 1, 2002